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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,076	06/06/2001	Chen W. Liaw	AREN-0239	6379

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	PAPER NUMBER
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/875,076	LIAW ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *77-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *77-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-76 have been canceled. Claims 77-101 are pending and under consideration by the Examiner.

2. Receipt of applicant's arguments filed on 11/21/2006 is acknowledged.

3. Applicant's arguments filed on 11/21/2006 have been fully considered and were non-persuasive. The issues remaining are stated below.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 101

5. Claims 77-101 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 3-6, of the previous Office action (3/21/03), pages 2-8 of the previous Office action (3/18/05), pages 2-8 of the previous Office action (10/13/05) and pages 2-10 of the previous Office action (5/19/06).

Applicants argue that the claimed invention has utility because hARE-2 can be used in screening methods for drug discovery. Applicants argue that the asserted utility is specific because identification of a ligand identified through a screening assay that employs hARE-2 can lead to modulation of cAMP or IP3 specifically in the substantia nigra and would lead one of ordinary skill in the art to recognize that the identified ligand can be used specifically to treat a disease or disorder of the substantia nigra such as Parkinson's disease. Applicants argue that the utility is substantial because the compounds identified in an assay employing hARE-2 can be administered to treat a disease or disorder of the substantia nigra such as Parkinson's disease and

this is a real world use. However, contrary to Applicants arguments, even though Applicants assert that hARE-2 is a GPCR expressed in the substantia nigra, Applicants have failed to demonstrate whether hARE-2 affects the level of cAMP or IP3. Applicants have cited Hulley et al (1995) to show that the viability of neurons in the substantia nigra is sensitive to the level of intracellular cAMP. Applicants have also cited Berridge et al (1993) to show that elevation of intracellular IP3 can lead to an elevation of intracellular calcium. However, Applicants have failed to demonstrate that the instant hARE-2 is associated with any of these second messenger systems.

All GPCRs are excellent targets for screening for drugs but the instant specification fails to associate hARE-2 with a particular ligand. Will activation of hARE-2 be detrimental or beneficial? Will inhibiting hARE-2 be detrimental or beneficial? Further experimentation is required to associate a specific disease or dysfunction with the claimed receptor.

The specification on page 27, Table C, discloses that hARE-2 are expressed in the cerebellum left, cerebellum right and substantia. However, the presence of the receptor in diseased tissue is not disclosed. The presence of the receptor at elevated concentrations in diseased tissue compared to normal tissue is not disclosed. The specification fails to disclose whether the receptor is present at elevated concentrations in diseased tissue compared to a normal tissue and how it can be used to correlate location to function and indicate the receptor's physiological role/function and create a treatment regimen, including but not limited to, a disease associated with that function/role.

The specification discloses that the claimed receptor is expressed in the substantia nigra. All Applicants' arguments are based on the receptor being expressed in the substantia nigra.

However, the presence of hARE-2 in the substantia nigra suggests a function for hARE-2 in the substantia nigra. Identification of the ligand for the receptor will help to clarify its function. Therefore, the function of hARE-2 needs to be clarified. Knowing the tissue distribution of a GPCR and its second messenger does not automatically mean that its function is known.

It is clear from the instant specification that the nucleic acid encoding the protein is what is termed an "orphan receptor" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. The specification discloses that the instant hARE-2 protein has 53% homology to GPR27. There is little doubt that after complete characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicants claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct, 1966)*, in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the Court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The Court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists

in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claim is drawn to a nucleic acid which encodes a protein of as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as a human G protein-coupled receptor, or the cDNA encoding it, the instant invention is incomplete. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious "patentable" use for it. To employ a protein of the instant invention in the identification of substances which inhibit its activity is clearly to use it as the object of further research which has been determined by the Courts to be a non-patentable utility. Since the instant specification does not disclose a "real world" use for the human , then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful. Applicants assertion that hARE-2 can be used in screening in drug discovery is not a specific utility because a screening method for drugs is applicable to a general class of receptors. Thus though Applicants have disclosed a general utility for hARE-2 such disclosure is not relevant to the question of specific utility.

The Examiner is not disputing that the claimed invention encodes a GPCR but that said GPCR does not have a specific , substantial and credible utility. Although the claimed receptor has been shown to be expressed in the substantia nigra there is no disclosure of the specific association with diseases such as Parkinson's disease. This determination requires further research. Furthermore, no agonists or antagonists of hARE-2 have been disclosed which can be

used to support a specific, substantial and credible utility. The determination of said ligands and their specific use requires further research. When the claimed GPCR is compared to Example 12 of the Revised Interim Utility Guidelines Training Materials said GPCR has no specific disclosed function or specific ligands that can be used to support utility. Since neither the specification nor the art of record disclose any activities or properties that would constitute a real world context of use for the claimed hARE-2, further experimentation is necessary to attribute a utility to the claimed hARE-2.

Claim rejections-35 USC § 112, first paragraph

6. Claims 77-101 are also rejected under 35 U.S.C. 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 3-6, of the previous Office action (3/21/03), pages 2-8 of the previous Office action (3/18/05), pages 2-8 of the previous Office action (10/13/05) and page 10 of the previous Office action (5/19/06).

Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

No claim is allowed.

Claims 77-101 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
December 19, 2006